

REMARKS

Summary of the Amendment

Claims 22-75 are currently pending, with claims 22, 74 and 75 being in independent form.

Summary of the Official Action

In the instant Office Action, the Examiner indicated on the form PTO-326 that the drawings filed May 9, 2002 were objected to and disapproved. However, the Examiner failed to explain any particular reason for this objection and disapproval. Next, the Examiner rejected numerous claims under section 112 first paragraph as inconsistent with the original claims. Additionally, claims 22-75 were rejected as indefinite for various reasons. Finally, claims 22-75 were rejected over the art of record. By the present remarks, Applicant submits that the rejections are improper and/or have been overcome, and respectfully requests reconsideration of the outstanding Office Action and allowance of the present application.

Request For Clarification Regarding Objection to the Drawings

The Examiner indicated on the form PTO-326 that the drawings filed May 9, 2002 were objected to and disapproved. However, the Examiner failed to explain any particular reason for this objection and disapproval.

P21742.A07

Applicant submits that the drawings are in compliance with current USPTO rules.

In view of the above, Applicant requests that the Examiner reconsider and withdraw the form PTO-326 objection to the drawings and indicate that the drawings as proposed to be amended are acceptable under the Patent Office Rules.

Traversal of the Section 112, first paragraph, rejection

Claims 24, 45 (interpreted instead as 25) , 27, 32, 33, 34-36, 41, 42, 48-63, 74 and 75 were rejected under 35 U.S.C. § 112, first paragraph, as being insufficiently described in the specification and as inconsistent with the original claims. Applicant respectfully disagrees.

Applicant submits that claims 22-75 recite features substantially similar to original claims 1-21. Moreover, the Examiner has failed to point to a single feature that is not recited in the original claims and/or that is not fully supported by the specification.

Additionally, Applicant submits that the Examiner's asserted basis for this rejection is entirely improper since there is no requirement under section 112, first paragraph, that all claims be consistent with claims that were originally filed. Moreover, even assuming that this was a requirement under section 112, first paragraph, Applicant submits that, contrary to the Examiner's assertions, the above-noted claims are clearly and entirely consistent with the original claims.

Finally, Applicant submits that one having ordinary skill in the art having read the

P21742.A07

specification and drawings would have no difficulty understanding the description of the invention as recited in the claims.

Accordingly, Applicant requests that the Examiner reconsider and withdraw this rejection.

Traversal of the Section 112, second paragraph, rejection

Claims 22-75 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite in regards to certain limitations being indefinite, incorrectly worded, redundant, meaningless, unclear, etc.

Applicant respectfully traverses this rejection and each and every assertion made by the Examiner in this rejection. Applicant does not disagree that some limitations broadly encompasses the invention. Nor does Applicant dispute that some of the Examiner's suggestions could be adopted without significantly narrowing the claims. However, this is beside the point. Applicant is unaware of any requirement, under either the patent statutes or rules, requiring Applicant to rewrite the claims in a manner which would please the Examiner or to limit the invention to any particular or preferred disclosed embodiment. Applicant reminds the Examiner that if the claim limitations are clear and have support in the specification, they cannot be properly rejected as indefinite merely because the Examiner would prefer that the claims recite more detailed limitations.

Moreover, the Examiner has set forth no legal basis for requiring Applicant to limit the invention. Applicant submits that the requirement that the claims be interpreted in light of the specification provides sufficient basis for the definiteness of the claims. Finally, the Examiner is reminded that Applicant is entitled to the broadest reasonable interpretation permitted by the prior art, and that one of ordinary skill in the art, having read the specification, would understand what the claims define.

Finally, Applicant would like to make general comments in response to the Examiner's numerous grounds of rejection under 35 U.S.C. § 112, second paragraph. *The breadth of a claim is not to be equated with indefiniteness.* As concerns the breadth of a claim, the primary concern is the *scope* of the claim relative to the scope of enablement provided to one skilled in the art by the disclosure. Claims should not be rejected as unduly broad under 35 U.S.C. § 112, second paragraph, for non-inclusion of limitations dealing with factors which must be presumed within the level of one of ordinary skill in the art; the claims need not recite such factors where one of ordinary skill in the art to whom the specification and claims are directed would consider them obvious. *In re Skrivan*, 427 F.2d 801, 166 USPQ 85 (C.C.P.A. 1970).

Moreover, Applicant submits that excessive 35 U.S.C. § 112, second paragraph rejections, should not be used as a substitute for prior art in an attempt to try to get Applicant to narrow the claims. Rather, 35 U.S.C. § 112, second paragraph rejections, should pertain

to definiteness and clarity of the claims.

Furthermore, definiteness of claim language is always analyzed in light of the teachings of the prior art, the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art, and the level of skill of the artisan in that art (*In re Moore*, 439 F.2d 1232, 169 USPQ 236 (C.C.P.A. 1971)). The essential question to be asked under 35 U.S.C. § 112, second paragraph, is whether the scope of the invention sought to be patented can be determined from the language of the claims. If the answer is yes, then the claims should not be rejected as being indefinite based on the second paragraph of 35 U.S.C. § 112. In particular, claims should be analyzed to determine whether they define the invention with a reasonable degree of particularity, clarity, and distinctness. See Patent and Trademark Office, Office of Policy and Dissemination Training Materials on Special Topics, 35 U.S.C. § 112, Second Paragraph, provided by the U.S.P.T.O. Patent Academy to Examiners for training purposes (1998).

Thus, with respect to the above-noted formal rejections, Applicant traverses all grounds of the Examiner's rejection based on the notion that the Examiner is only attacking the scope of Applicants claims, not definiteness. As mentioned above, the breadth of a claim is not to be equated with indefiniteness.

Needless to say, Applicant is of the opinion, that the Examiner has misapplied 35 U.S.C. § 112, second paragraph, to Applicant's claims. The Examiner has burdened

P21742.A07

Applicant with excessive grounds of rejections and questions which do not apply to clarity of the claims, but instead deal with the scope and breadth of the invention claimed.

Overall, the questions the Examiner presents are questions which can and should be easily answered by applying basic claim interpretation rules and also relying on the instant disclosure. Applicant respectfully refers the Examiner to review the specification so that the questions he presents can be answered.

Accordingly, Applicant has reviewed each and every ground of rejection, and has addressed each ground which is properly presented under 35 U.S.C. § 112, second paragraph.

Accordingly, Applicant respectfully requests that the Examiner reconsider and withdraw the rejections of claims 22-75 under 35 U.S.C. § 112, second paragraph.

Traversal of Rejection Under 35 U.S.C. § 102(b)

Claims 22-75 were rejected as being anticipated by UK Patent No. GB 2 136 692 to SCHWEIKHART.

The Examiner asserted that this document discloses all of the features of these claims including, among other things, a prosthesis with the claimed structural features. Reconsideration of the above-noted rejection is respectfully requested.

Applicant respectfully submits that this document fails to disclose, inter alia, an implantable *breast prosthesis which is specific to either a right breast side or a left breast*

P21742.A07

side of a patient, and which comprises a soft pouch that is specific to either the right breast side or the left breast side of the patient, as recited in independent claims 22, 74 and 75.

Applicant notes that this document is clearly directed to a temporarily insert and clearly lacks any disclosure to a breast prosthesis (see lines 5-10 of page 1). Nor can it be said that this document discloses *a soft pouch*, much less, one that is *specific to either the right breast side or the left breast side of the patient*. Applicant reminds the Examiner that each and every claim recites a breast prosthesis including a soft pouch that is specific to either the right breast side or the left breast side. On the other hand, the device disclosed in SCHWEIKHART is disclosed as being a plastic body temporary insert that is “sufficiently rigid or dimensionally stable” (see lines 68-70 of page 1). It is also clear from Fig. 1 that the body is symmetrical and, therefore, clearly non-specific to either the right or left sides.

It is also noted that, contrary to the Examiner’s assertions, the various recited zones and points are clearly not disclosed in this document. Moreover, Applicant submits that the Examiner has mis-characterized this document and the claims, and further, has simply disregard most of the numerous features recited in the claims.

Appellant emphasizes that this document clearly lacks any disclosure with regard to an implantable breast prosthesis, much less, one that is *specific to either a right breast side or a left breast side of a patient*. Nor is the disclosed device *a soft pouch*, much less, one that is *specific to either the right breast side or the left breast side of the patient*. Contrary to the

P21742.A07

Examiner's assertion, the disclosed plastic body is clearly not a *breast prosthesis*, not a *soft pouch* and not *specific to either the right breast side or the left breast side of the patient*.

Applicant additionally submits that the Examiner has set forth no legal basis for disregarding and/or for not giving patentable weight to the above-noted recited features. Applicant submits that the Examiner is not free to disregard features which describe and limit the invention. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1306, 51 USPQ2d 1161, 1166 (Fed. Cir. 1999).

Applicant notes that, for an anticipation rejection under 35 U.S.C. § 102 to be proper, each element of the claim in question must be disclosed in a single document, and if the document relied upon does not do so, then the rejection must be withdrawn.

Finally, Applicant submits that claims 23-73 are allowable at least for the reason that these claims depend from an allowable base claim and because these claims recite additional features that further define the present invention. In particular, Applicant submits that no proper characterization or reading of this document discloses, or even suggests: that the filling material comprises one of a silicone gel and a physiological serum as recited in claim 23; that the soft pouch is asymmetrical in relation to a plane which passes through an upper zone of the soft pouch, a nipple area of the soft pouch and a lower zone of the soft pouch, when the soft pouch is implanted in the patient and filled as recited in claim 24; that the asymmetry is defined by a difference in dimensions between a first distance and a second

P21742.A07

distance defined by a plane passing through the inner zone, the nipple area and the outer zone, whereby the plane passing through the inner zone, the nipple area and the outer zone is perpendicular to a plane passing through the upper zone, the nipple area and the lower zone as recited in claim 25; that the first distance is different from the second distance as recited in claim 26; that the first distance is defined between an edge of the inner zone and a point in the nipple area and wherein the second distance is defined between an edge of the outer zone and the point in the nipple area as recited in claim 27; that a ratio r of the second distance to the first distance is less than or equal to 0.95 as recited in claim 28; that the ratio r is in the range of between 0.8 and 0.9 as recited in claim 29; that the ratio r is in the range of between 0.85 and 0.9 as recited in claim 30; that the ratio r is about 0.875 as recited in claim 31; that the soft pouch further comprises a rear outer zone adjacent the outer zone, and wherein the plane passes through the inner zone, the nipple area, the outer zone and the rear outer zone as recited in claim 32; that the prosthesis further comprises a third distance being defined between an edge of the rear outer zone and a point in the nipple area, whereby the first distance is defined between the point in the nipple area and an edge of the inner zone, the first distance and the third distance being at least one of equal to each other and very close to each other as recited in claim 33; that the asymmetry is defined by a difference in dimensions between a fourth distance and a fifth distance defined by a plane passing through the upper zone, the nipple area and the lower zone, whereby the plane passing through the

P21742.A07

upper zone, the nipple area and the lower zone is perpendicular to a plane passing through the inner zone, the nipple area and the outer zone as recited in claim 34; that the fourth distance is different from the fifth distance as recited in claim 35; that the fourth distance is defined between an edge of the upper zone and a point in the nipple area and wherein the fifth distance is defined between an edge of the lower zone and the point in the nipple area as recited in claim 36; that the fourth distance is greater than the fifth distance as recited in claim 37; that a ratio r of the fourth distance to the fifth distance is at least 1.1 as recited in claim 38; that the ratio r is in the range of between 1.1 and 2 as recited in claim 39; that the ratio r is in the range of between 1.3 and 1.5 as recited in claim 40; that the soft pouch further comprises an outer overlap portion in an area of the outer zone, when the soft pouch is implanted in the patient and filled as recited in claim 41; that the outer overlap portion extends to each of the upper zone and the lower zone as recited in claim 42; that the outer overlap portion comprises an anterior surface which forms an obtuse angle ϕ relative to the posterior surface as recited in claim 43; that the angle ϕ is greater than 95 degrees as recited in claim 44; that the angle ϕ is greater than 100 degrees as recited in claim 45; that the angle ϕ is in the range of between 91 degrees and 120 degrees as recited in claim 46; that angle ϕ is 115 degrees as recited in claim 47; that the posterior surface is at least one of concave and curved as recited in claim 48; that the posterior surface is at least one of concave and curved between an edge of the inner zone and an edge of the outer zone as recited in claim 49; that

P21742.A07

the posterior surface is at least one of concave and curved at least in an area of the inner zone as recited in claim 50; that a distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone is at least 5 mm as recited in claim 51; that a distance between a plane extending through an edge of the inner zone and an edge of the outer zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the inner zone and the edge of the outer zone is at least 1 cm as recited in claim 52; that the posterior surface is at least one of concave and curved between an edge of an upper zone and an edge of a lower zone as recited in claim 53; that the posterior surface is at least one of concave and curved at least in an area of an upper zone as recited in claim 54; that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is at least 1 mm as recited in claim 55; that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is at least 2 mm as recited in claim 56; that a distance between a plane extending through an edge

P21742.A07

of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the posterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is in the range of between 3 mm and 6 mm as recited in claim 57; that the anterior surface is at least one of curved and convex as recited in claim 58; that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is in the range of between 3 cm and 7 cm as recited in claim 59; that a distance between a plane extending through an edge of an upper zone and an edge of a lower zone and a parallel plane extending through a point on the anterior surface that is farthest away from the plane extending through the edge of the upper zone and the edge of the lower zone is on the order of 5 cm as recited in claim 60; that at least a portion of the posterior surface is one of less deformable and more rigid than another portion of the soft pouch as recited in claim 61; that the portion of the posterior surface that is one of less deformable and more rigid than another portion of the soft pouch has a thicker surface than the other portion of the soft pouch as recited in claim 62; that the posterior surface and the anterior surface form an angle δ in an upper zone of less than 70 degrees when the soft pouch is implanted and filled with the filling material as recited in claim 63; that the angle δ is less than 65 degrees as recited in claim 64; that the angle δ is less than 60 degrees as recited in

P21742.A07

claim 65; that the angle δ is about 40 degrees as recited in claim 66; that the angle β is less than 65 degrees as recited in claim 67; that the angle β is less than 60 degrees as recited in claim 68; that the angle β is about 40 degrees as recited in claim 69; that the soft pouch comprises an elastomer as recited in claim 70; that the elastomer comprises silicone as recited in claim 71; that the soft pouch is adapted to be filled with the filling material either before or after being implanted into the patient as recited in claim 72; and that the implantable breast prosthesis comprises an expansion prosthesis as recited in claim 73.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this rejection and further requests that the above noted claims be indicated as allowable.

CONCLUSION

In view of the foregoing, it is submitted that none of the references of record, either taken alone or in any proper combination thereof, anticipate or render obvious Applicant's invention, as recited in each of claims 22-75. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Further, any amendments to the claims which have been made in this response and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered to have been made for a purpose unrelated to patentability, and no

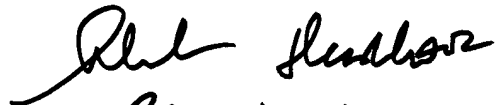
P21742.A07

estoppel should be deemed to attach thereto.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

The Commissioner is hereby authorized to charge any additional fee necessary to have this paper entered to Deposit Account No. 19-0089.

Respectfully submitted,
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